Abbott GmbH
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DIAGNOSTICS

Abbott

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

Date Issued October 29, 2020

Product

Product Description	List Number	Lot Number	US UDI	EU UDI
ARCHITECT EBV VCA IgM Calibrator	3P66-01	08159BE00	Not applicable	Not applicable

Explanation

This letter is to inform you of a Product Recall for the ARCHITECT EBV VCA IgM Calibrator lot 08159BE00 and to provide instructions on the actions your laboratory must take.

Abbott has identified the ARCHITECT EBV VCA IgM Calibrator lot 08159BE00 may show reduced RLU (Relative Light Units) signal. This reduced RLU signal may cause a decrease in cutoff RLU values in assay calibration resulting in:

- Upward shift in Quality Control S/CO values
- Non-reactive to false grayzone patient results in the range of 0.50 - 0.56 S/CO
- Grayzone to false reactive patient results in the range of 1.00 - 1.13 S/CO

The effect of decreased cutoff RLU values is observed when using the ARCHITECT EBV VCA IgM Calibrator lot 08159BE00 and is independent from the ARCHITECT EBV VCA IgM reagent lot used.

The root cause for this issue is under investigation for an appropriate corrective action.

Patient Impact

The shift in S/CO values may potentially lead to false grayzone or false reactive patient results when using the ARCHITECT EBV VCA IgM Calibrator lot 08159BE00.

Necessary Actions

- Immediately discontinue use of, and destroy, any remaining inventory of ARCHITECT EBV VCA IgM Calibrator lot 08159BE00 according to your local guidelines and your laboratory procedure.

- In the event you are currently using or have inventory of this lot, immediately contact Customer Support for replacement material.

- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.

Necessary Actions continued

- Complete and return the Customer Reply Form.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.